

New claims 35-37 are presented herewith to complete the record for consideration by the Examiner and to present additional embodiments of alloy. Support for these new claims can be found in the application as filed at page 7, lines 12-18 and ~~page 14, lines 26-30~~.

The rejections of record are addressed below in the order presented in the Office Action.

The Office Action objects to the disclosure. Applicants have amended the specification to include the unit of measurement omitted from page 5, line 22. Applicants respectfully request withdrawal of this objection.

Claim 21 is rejected under 35 USC § 112, second paragraph, as indefinite. The Office Action argues that Claim 21 is missing a unit of measure for the value of 120. Claim 21 is amended to recite the correct unit measure. This amendment does not narrow any claim recitations but merely recites the unit of measurement. Thus, this amendment does not affect the scope of protection afforded Applicants, including any scope available under the Doctrine of Equivalents.

Claims 17-21 are rejected under 35 USC § 102(e) as anticipated by U.S. Patent No. 5,891,191 to Stinson. Applicants offer the following comments.

Applicants' claimed invention is directed to a biocompatible cobalt-base alloy comprising chromium and molybdenum. In one aspect, the alloy includes from about 26 to about 28 weight percent chromium, from about 5 to 6 weight percent molybdenum, up to about 1 weight percent manganese, up to about 1 weight percent nickel, up to about 0.75 weight percent iron, and up to about 0.07 weight percent carbon with the remainder being cobalt and impurities. See new Claim 35.

As discussed in the present application, prior Co-Cr-Mo alloys form a hard intermetallic compound known as sigma phase. Sigma is a very hard and brittle compound. It has been found that second phase particles on the surface of conventional alloy implant structures can detach from, or out of, the alloy surface leaving a pitted surface. In turn, the hard second phase particles and the pitted ball surface can generate substantial abrasive wear of a joint implant ball surface, *in vivo*. It has been found that elimination of sigma phase particles from Co-Cr-Mo alloys can substantially improve the wear properties and fatigue properties of the alloy. In contrast to prior alloys, the alloy of the invention is essentially free of carbide, nitride, and sigma second phase

particles.

To avoid formation of insoluble sigma phase materials, the applicants have found that manipulation of the ratios of materials used in forming the alloys can reduce the formation of such insoluble sigma phase materials. For example, the applicants have found that the ratio of the weight percent of cobalt to the sum of the weight percent of chromium plus one-half the weight percent of molybdenum should be maintained in the range below about 0.450. See new Claim 37.

Further, the Applicants have found that increased amounts of silicon, molybdenum and chromium can lead to increased carbide and sigma phase particles. In general, the quantity of carbon present in the claimed invention should be below about 0.07 weight percent in order to prevent the formation of second phase carbide particles. However, the exact limits on carbon will vary depending on the quantities of other alloy components in the melt. Thus, carbon can be maintained in solution in higher quantities, without the formation of insoluble carbides when silicon, molybdenum and chromium components are maintained in lower levels in the alloy.

Still further, the applicants have found that nitrogen compounds can react to form blocky second phase TiN particles in the alloys, even in the presence of very small amounts of titanium. Thus titanium content restricted below 0.02 wt. % when nitrogen is added can prevent formation of such undesirable second phase TiN particles. See new Claim 36.

The Stinson patent is directed to processes for cold drawing a traditional cobalt-chromium-molybdenum alloy to form filaments. The filaments are then formed into a stent.

The alloy taught by Stinson is prepared according to traditional methods. Stinson does not recognize, much less teach, the importance of the amounts of materials used with respect to the formation of sigma second phase particles. Indeed, the Stinson alloy contains a significant amount of silicon, one of the components discovered by the Applicants to lead to the formation of carbide and sigma phase particles. The amount of silicon present in the Stinson alloy is high (one percent). Therefore, the alloy of Stinson contains carbide and sigma phase particles as shown in Figures 1 and 2 of Applicants' specification. As a result, the claimed alloys and the Stinson alloys differ in composition and structurally.

Further, Stinson describes the Co-Cr-Mo alloy generally. The only specific formulation

is given in column 5, lines 54-57. According to this formulation, cobalt is present in an amount of approximately 62%, chromium 26% and molybdenum 6%. Given these amounts, the ratio of cobalt to chromium plus one-half molybdenum is 0.467, well above the ratio of Applicants' invention as recited in Claim 37.

The alloy of Stinson differs structurally from the claimed invention. By its very nature and composition, the alloy of Stinson would naturally contain carbide and sigma phase particles and is therefore different than Applicants' claimed invention.

Further, as discussed in the present application, it was once thought that second phase carbide particles resulted in a stronger alloy. The present application includes comparative data demonstrating the structural and compositional differences between an alloy prepared using conventional methods (such as that taught in Stinson) and the alloys of the present invention. Specifically, in Example 1 of page 18, Applicants have shown that increased amounts of molybdenum, silicon, and chromium result in large carbide and larger blocky sigma phase particles. These results are also shown in Figures 1-4 of the present application.

Also, as provided in Example 5 on page 22, Applicants have shown that the alloys of the present invention do not have compromised tensile properties as a result of the change in composition. The tensile properties of the present invention are comparable to those of prior art alloys despite the almost complete absence of second phase carbide particles in the bar stock. In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

Claim 22 is rejected under 35 USC § 103(a) or (e) as being unpatentable over Stinson. Stinson is not directed to a biocompatible alloy essentially free of carbide, nitride and second phase particles. As stated above, by the very nature of such a mixture of components, the alloy of Stinson would naturally contain carbide and sigma second phase particles. Further, Stinson nowhere describes the grain size of its alloy. Not only does Stinson not teach grain size, however, as noted above, Applicants' claimed invention differs in structure and composition from the conventional alloys as taught in Stinson. Applicants accordingly respectfully request withdrawal of this rejection as well.

The rejections of record having been addressed in full in the foregoing, Applicants respectfully request an indication of the allowability of the claimed invention. Should the

Examiner have any questions regarding the foregoing, it is respectfully requested that he contact the undersigned at his convenience.

It is noted that an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement filed September 13, 2000 was returned to Applicants' representative with the Office Action. However, one reference was not initialed. Accordingly, Applicants submit herewith under separate cover an additional Form 1449. It is requested that an initialed copy of the Form 1449 be forwarded to the undersigned with the next communication from the PTO. In order to facilitate review of the reference by the Examiner, a copy of the Information Disclosure Statement, Form 1449, and a copy of the cited reference including an English abstract are attached hereto.

In re: Fehring *et al.*
Appl. No.: 09/660,948
Filed: September 9, 2000
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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

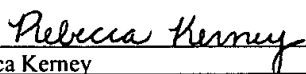


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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, Washington, DC 20231.


Rebecca Kemey

Version with Markings to Show Changes Made:

In the Specification:

On page 5, lines 20-25, please amend the paragraph as follows:

According to a first aspect of the invention, artificial implant components are formed of a biocompatible metal alloy having a hardness greater than about 40 Rc, a yield strength greater than about 120 Ksi, and a grain size finer than ASTM 10, and which is essentially free of carbide, nitride, and sigma particles. Preferably, the alloy is an essentially single-phase alloy, i.e., the alloy is essentially free of all second phase particles.

On page 9, lines 21-23, please amend the paragraph as follows:

Figure 15 schematically illustrates a precision laser inspection apparatus capable of identifying surface defects, of a size greater than 5 micrometers, on the articulating spherical surface of the ball components of joint implants[.]; and

On page 13, lines 15-27, please amend the paragraph as follows:

Accordingly, artificial implant components according to the present invention are formed of a biocompatible metal alloy substantially free of carbide and sigma second phase particles and preferably essentially free of any second phase particles. The implant and components of the invention are particularly desirable for use in forming articulating implant components in artificial hip, knee, shoulder, ankle, elbow and other joints because they do not generate second phase particles, and/or pitted surfaces. Such articulating components include the ball component 52 of the conventional hip implant 50 illustrated in Figure 16. In addition, single phase alloys are also desirably used to form non-articulating elements of joint implants such as implant stems and nails, screws, and plates, because of the alloy's improved stability and/or strength. The alloys of the invention are also desirably used to form implant components and fixation structures that are positioned in juxtarticular locations in the body since release of second phase particles may otherwise enhance loosening of implants via various biological responses, and may cause

chemical changes in body fluids and tissues. Examples of such components are illustrated in Figure 16 and include the stem 54 of the hip implant 50, and the fixation devices 60 which include a screw 62, a nail or pin 64, and a fixation plate 66.

In the Claims:

Please amend the claims as follows:

22. (Amended) The biocompatible metal alloy of Claim 20, wherein said alloy has a yield strength greater than about 120 Ksi.